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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,758	09/29/2006	Yoshihiro Nomura	296946US0PCT	5292

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EXAMINER	
TSAY, MARSHA M	

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/594,758	NOMURA ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9,20-25 and 30-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9,20-25 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 16, 2010 has been entered.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 6, 10-19, 26-29 are canceled. Claims 1-5, 7-9, 20-25, 30-34 are currently under examination.

Priority: The request for priority to JAPAN 2004-107286, filed March 31, 2004, is acknowledged. A certified copy of the foreign priority document has been filed in this case on September 29, 2006, and is in a non-English language.

Objections and Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-9, 20-25, 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1, 8, and 20 have been amended to recite the negative limitation "not containing a reducing agent." However, as noted in MPEP 2173.05(i), any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 2-5, 7, 9, 21-25, 30 are included in this rejection because they are dependent on claims 1, 8 and 20.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-9, 20-25, 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schrooyen et al. (US 7169896; previously cited) in view of Mullner et al. (WO 0236801 abstract; previously cited). For examination purposes, claim 1 has been interpreted as: a method for producing solubilized keratin comprising (a) hydrolyzing a keratin raw material that has a water content ranging from 20 to 80% by weight, in an alkali solution not containing a reducing agent; (b) neutralizing the hydrolyzate liquid containing solubilized keratin; and (c) extracting a solubilized keratin from the supernatant, wherein said keratin has an average molecular weight of 8,000 to 13,000 Da.

In col. 15, lines 50-67, Schrooyen et al. disclose a process for producing partially modified and partially hydrolyzed keratin comprising the steps of (a) solubilizing keratin in an aqueous solution containing a reducing agent and at an alkaline pH between 10 and 13.5, at a temperature of at least 40° C; (b) partially modifying the –SH groups of the solubilized keratin (i.e. in this instance, alkylation); (c) and obtaining solubilized keratin that has a molecular weight (MW) between 1 kDa and 10.4 kDa. Regarding the solubilizing step of (a), it should be noted that Schrooyen et al. disclose that the solubilizing conditions can also be achieved, alternatively, by physical hydrolysis (col. 7 lines 50-55, col. 8 line 58 to col. 9 line 10). Therefore, the aqueous solution would not necessarily have to contain a reducing agent. Regarding the modification step of (b), Schrooyen et al. further disclose that modification of the solubilized keratin is not limited to alkylation, but can also include treating said keratin with hydrogen peroxide, chloroacetic acid, etc. (col. 7 lines 1-10). Schrooyen et al. further disclose that the aqueous alkaline solution, used in the solubilization step of (a), can contain an alkali metalsuphide or ammonium sulphide between 0.05 M and 1.0 M, or a combination of 2-

mercaptoethanol and sodium hydroxide (col. 4 lines 41-47). The solubilization step of (a) can take between 10 minutes to 24 hours (col. 4 lines 60-65). The keratin starting material can be poultry feathers (abstract). Schrooyen et al. also disclose that the keratin material can be pre-treated prior to the hydrolysis reaction (col. 8 lines 58-67) but do not teach a hydrous state of 20 to 80%.

Mullner et al. disclose keratin protein hydrolysates obtained from keratinous waste (i.e. wool, feathers, hooves, etc.) are suitable for use in cosmetic compositions (p. 3). Mullner et al. disclose that the substrate is a natural proteinaceous product preferably with a water content of 5-99 weight %, especially a substrate containing keratin (p. 4). The final keratin protein product contains substantially no toxic constituents (p. 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Schrooyen et al. by substituting the keratin material (having a water content in the range of 5-99 wt %) of Mullner et al. for the keratin starting material used in Schrooyen et al. for a process of producing a solubilized keratin comprising a solubilization step in an alkali solution not containing a reducing agent, a treatment step with hydrogen peroxide or acid, and obtaining a solubilized keratin having a MW between 1 kDa and 10.4 kDa, as disclosed by Schrooyen et al. (claims 1-5, 7-9, 20-25, 30-34). The motivation to do so is given by Mullner et al., which teach that using a keratinous substrate having a water content in the range of 5-99 weight % in a protein hydrolysis process can eliminate toxic constituents in the final keratin protein product, therefore, it would be reasonable for one of ordinary skill to want to improve upon the process of Schrooyen et al. by using a starting material that will reduce the toxicity of the end product.

Regarding step (b), it would be reasonable for one of ordinary skill to know that the modification step of Schrooyen et al. would be functionally equivalent to the instant neutralization step since Schrooyen et al. disclose that said modification step is performed after a hydrolysis step in an alkali solution and said modification step can be performed using the same agents as the instant invention (i.e. hydrogen peroxide or acid).

Regarding the limitation of not containing a reducing agent (claims 1, 8, 20), as noted above, Schrooyen et al. disclose that the solubilizing conditions can also be achieved, alternatively, by physical hydrolysis (col. 7 lines 50-55). Therefore, the aqueous solution would not necessarily have to contain a reducing agent.

Regarding the product claims of claims 8, 9, 34, the keratin product of Schrooyen et al. would be functionally equivalent to the instant keratin product because Schrooyen et al. disclose variations of the instant active steps (i.e. hydrolyzing and neutralizing steps that use the same solutions as the instant invention) to obtain a keratin product that meets the scope of the instant MW range.

Regarding claim 33, it should be noted that Schrooyen et al. disclose that the aqueous alkaline solution, can contain an alkali metalsuphide or ammonium sulphide between 0.05 M and 1.0 M, or a combination of 2-mercaptoethanol and sodium hydroxide. It would be reasonable for one of ordinary skill to know that other equivalent metal hydroxides known in the art can be substituted in for the sodium hydroxide (i.e. calcium hydroxide, potassium hydroxide).

In their remarks, Applicants assert that **(1)** Schrooyen et al. do not disclose or suggest a keratin extraction process that does not use a reducing agent. **(2)** Mullner et al. do not disclose

the range 5% to 99%, is generally directed to extruded protein hydrolysates, and does not mention a method of producing solubilized keratin. Nevertheless, even if Mullner et al. did teach keratin raw materials having a water content between 5% and 99%, it still did not provide a reasonable expectation of success for the subrange of water content required by the claims, namely 20-80 wt %. Applicants point to the declaration submitted August 31, 2009, where selection of a keratin raw material having a water content between 20% and 80% results in superior decomposition by hydrolysis and substantially better yield of hydrolysate compared to otherwise identical processes using keratin raw material containing 5%, 15%, 90% or 95% water. Neither Schrooyen et al. nor Mullner et al. suggested or provided a reasonable expectation of success for this result and can provide no motivation for selecting this range of water content. (**3**) Applicants further assert that the claimed process does not use a reducing agent (see pages 8-10 of Applicants' remarks of August 16, 2010).

Applicants' arguments have been fully considered but they are not persuasive.

(**1**) **Response**: It should be noted that a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Further, "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). MPEP 2141.02.

As noted above, Schrooyen et al. disclose that the solubilizing conditions can also be achieved, alternatively, by physical hydrolysis (col. 7 lines 50-55, col. 8 line 58 to col. 9 line 10). Therefore, the aqueous solution would not necessarily have to contain a reducing agent.

(2) Response: As previously noted, Mullner et al. is cited to note that the starting material can be a keratin material having a water content of 5-99 wt %, and not to the protein hydrolysis process that is used. Therefore, it would be reasonable for one of ordinary skill to understand that a "substrate" is a starting product from which a hydrolysis process is carried out. Regardless of the protein hydrolysis process that is used (i.e. enzymatic hydrolysis or alkaline hydrolysis), it would be reasonable for one of ordinary skill to know that any appropriate keratin material can be used as the starting material for the protein hydrolysis process.

As previously noted, the motivation to substitute in the keratin material having a water content of 5-99 wt % of Mullner et al. is given by Mullner et al. which disclose that using a keratinous substrate having a water content in the range of 5-99 weight % in a protein hydrolysis process can eliminate toxic constituents in the final keratin protein product. Further, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by Applicant. See, e.g., In re Kahn, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention); Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1323, 76 USPQ2d 1662, 1685 (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its

teachings."); In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991). In this instance, the fact that Appellants use a keratin raw material having a water content of 20-80 wt% in order to achieve superior results does not alter the conclusion that its use in the prior art would be prima facie obvious from the purpose disclosed in the Mullner et al. reference (i.e. to eliminate toxic constituents).

Regarding Applicants' assertion that Mullner et al. do not suggest selecting the narrow range of 20-80 wt % from 5-99 wt %, Applicants are reminded that the instant range of 20-80 wt % is within the scope of the 5-99 wt % range of Mullner et al.; therefore, it would be obvious for one of ordinary skill to easily substitute in a keratinous substrate having a water content of 20%, 30%, 40%, 50%, 60%, 70%, or 80% (by weight) because these weight percentages are within the range disclosed by Mullner et al., even if used for a different purpose.

(3) **Response**: See the response of (1). Specifically, Schrooyen et al. disclose that the solubilizing conditions can also be achieved, alternatively, by physical hydrolysis (col. 7 lines 50-55, col. 8 line 58 to col. 9 line 10). Therefore, the aqueous solution would not necessarily have to contain a reducing agent.

For at least these reasons, the claims remain rejected under 103(a).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marsha M. Tsay/
Primary Examiner, Art Unit 1656

April 9, 2011